

# AMERICAN COLLEGE of CARDIOLOGY



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June 1, 2000

## Docket No. 00N—1256

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
rm. 1061  
Rockville, MD 20852

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**RE: Over-the-Counter Drug Products; Public Hearing; notice of participation  
(Docket No. 00N—1256)**

The American College of Cardiology (ACC) hereby gives notice of its intent to participate in the Food and Drug Administration's public hearing on over-the-counter drug products to be held on Wednesday, June 28, and Thursday, June 29, 2000 at the Gaithersburg Holiday Inn. An ACC member will deliver oral comments discussing potential guidelines for considering moving certain cardiovascular drugs to over-the-counter (OTC) status. When we apply these guidelines to such cardiovascular drugs as diuretics, antihypertensive agents, and cholesterol-lowering drugs, we find that they would most likely not qualify for OTC status. We estimate that we will require twenty (20) minutes to deliver our comments.

The ACC is a 24,000-member non-profit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, leadership in the development of standards and guidelines, and the formulation of health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

Please contact Alan Yount, Assistant Director for Regulatory and Legal Affairs, at 301-493-2352 or [ayount@acc.org](mailto:ayount@acc.org) if you have any questions regarding our participation.

Sincerely,

George A. Beller, M.D., F.A.C.C.  
President

cc: Lawrence J. Laslett, M.D., F.A.C.C.  
Robert J. Cody, M.D., F.A.C.C.  
C. Noel Bairey Merz, M.D., F.A.C.C.  
Christine McEntee  
Karen Collishaw  
Alan Yount

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